

## **Remarks**

Newly added claims 98-104 are presented to the Examiner in this Draft Amendment for the purpose of discussion.

The Applicants will explain support for newly added claims 98-104 in a formal submission to follow discussions with the Examiner in the event the claims are considered potentially allowable.

Each of the Examiner's objections or rejections is addressed below in the order they were presented in Paper No. 11.

### **Rejection Pursuant to 35 U.S.C. § 112, First Paragraph (Written Description)**

The Examiner rejects claims 39 and 58-94 pursuant to 35 U.S.C. § 112, first paragraph. In the Examiner's view, the specification does not adequately convey to a skilled artisan that the Applicants were in possession of the claimed invention at the time the application was filed. The Examiner included two apparently alternative grounds for this rejection, namely 1) that the claims include within their scope more genes than are adequately described in the specification and 2) that the claims include within their scope more disorder-associated polymorphisms (DAPs) than are adequately described in the specification.

Although the Applicants believe that the Examiner's rejection is unfounded, they need, for business reasons, to obtain allowance of whatever claims the Examiner may believe are allowable as soon as possible. To this end, the Applicants propose substituting claims 98-104 (and likely several more dependent claims to be included in a possible subsequent formal submission) in place of the pending claims. These proposed claims are directed solely to the DAPs that are explicitly described in the specification in the list spanning pages 11-13. The Applicants believe that the Examiner's written description rejection is clearly not applicable to claims 98-104 and wish to discuss this issue with the Examiner prior to formal submission.

### **Rejection Pursuant to 35 U.S.C. § 112, First Paragraph (Enablement)**

Claims 39 and 58-94 stand rejected pursuant to 35 U.S.C. § 112, first paragraph. In the Examiner's view, the specification does not adequately teach a skilled artisan how to practice the invention throughout its full scope. The Examiner opined that the scope of genes and DAPs recited in the rejected claims requires undue experimentation by a skilled artisan in order to enable that artisan to practice the invention recited in those claims.

The Applicants respectfully believe that the Examiner's rejection is in error. Nonetheless, in order to obtain quick allowance of subject matter that may be most clearly allowable, the Applicants have restricted proposed new claims 98-104 to the genes and DAPs explicitly described in the specification in the list spanning pages 11-13. The Applicants believe that the Examiner's enablement rejection is clearly not applicable to claims 98-104 and wish to discuss this issue with the Examiner prior to formal submission.

The Examiner suggested in the Office Action (see the paragraph bridging pages 13 and 14 of Paper No. 11) that the specification does not adequately teach how an artisan should determine "whether occurrence of a DAP in a gene is correlated for the administration of a greater do[se] of an anti-oxidant." The Applicants respectfully disagree. Paragraph [0043] (using the numbering in the as-filed specification) of the specification discloses that each DAP in one of the indicated genes is indicative of increased susceptibility to oxidative stress, which is indicative that a greater dose of anti-oxidant should be administered. The paragraphs subsequent to [0043] indicate that different DAPs can have different degrees of importance; nonetheless, all of the DAPs disclosed in the specification (and recited in proposed claims 98-104) as being informative for oxidative stress. The Applicants respectfully contend that a skilled artisan would understand from the specification that occurrence of each DAP in the list spanning pages 11-13 is an independent indication of additional susceptibility to oxidative stress and that occurrence of multiple DAPs in the list is indicative of a greater need for anti-oxidant administration than occurrence of a lesser number. The Applicants respectfully contend that it is not necessary for the claimed invention that the specification provide a mathematical formula correlating the occurrence of each listed DAP with the precise incremental dosage of every possible anti-oxidant. Rather, it is sufficient that a skilled artisan

can recognize that occurrence of a greater number of listed DAPs indicates a greater need for anti-oxidant than does occurrence of a lesser number.

In the telephone interview conducted on 15 January 2004 with the Examiner and the Applicants' undersigned representative, the Examiner requested further information regarding how an appropriate dose of an anti-oxidant composition might be selected. The Applicants suggest that selection of an absolute value for such a dose (e.g., "x" grams of antioxidant "A") is not required to be taught in the specification. Instead, the Applicants respectfully suggest that an skilled artisan reviewing the specification would understand that the information gleaned from the methods disclosed in the specification would indicate the relative need of the individual tested to receive more or less (relative to a normal individual) of an antioxidant, and that exact dosing would depend on the identity of the antioxidant selected. The Applicants respectfully suggest that the disclosure in the specification is sufficient to teach the skilled artisan to use the claimed methods, and that the Examiner's rejection should be withdrawn.

## Summary

For the reasons set forth above, the Applicants respectfully contend that proposed new claims 98-104 includes only allowable subject matter. The Examiner is requested to consider the proposed claims and to discuss them with the Applicant's undersigned telephone representative during the telephonic interview scheduled for 10:00 a.m. on 15 January 2004. The Examiner's agreement to participate in the interview and his flexibility regarding scheduling are sincerely appreciated.

Respectfully submitted,

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(Date)

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